K081379

510(k) Summary

superDimension, Ltd.
Special 510(k)
Changes to inReach System Software Version 5.0

JUN 11 2008

Date Prepared:

05/15/2008

510(k) Applicant:

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510(k) Application Correspondent:

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Name of Device :

Trade Name :	- superDimension®/Bronchus - inReach™ System
Common Name:	Bronchoscope
Classification Name:	Computed tomography x-ray system 21 CFR Part 892.1750 Product code JAK

Equivalent Legally-Marketed Device:
inReach System, K080271

Description:

The inReach System is a device that guides a bronchoscope and bronchial tool to a target in or adjacent to the bronchial tree on a path indicated by CT scan, and visualizes the target and the interior of the tree. The inReach System also enables the placement of radiosurgical and dye markers into soft lung tissue to guide radiosurgery and thoracic surgery.

Intended Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Summary of Characteristics Compared to Predicate Device:

The planning software has been modified to add the generation and visualization of a three-dimensional (3D) bronchial tree map, an enhanced graphical user interface (GUI), improved 3D-pathway planning and verification, the addition of the product brand name (inReach™), and a splash screen.

The procedure software has been modified to include the 3D-Map view of the bronchial tree, GUI enhancements, increased navigation ability with navigation guidance enhancements, a backup/cleanup utility, the addition of the product brand name (inReach™), and a splash screen.

Modifications are being made to the Instructions for Use (inReach User Manual) to reflect the aforementioned software modifications.

No changes are being made to the hardware or intended use, or technological characteristics of the current marketed device.

Performance Data:

The planned modifications were subjected to the superDimension design control process. Appropriate labeling changes, risk analysis, software and design validations were performed to assure the inReach System continues to meet the its intended use.

Clinical Data:
Clinical tests were not required to validate the changes to the inReach System.

Conclusion:
The inReach System is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2008

SuperDimension, Ltd.
% Mr. Jonathan Kovach
Vice President, Quality and Regulatory Affairs
SuperDimension, Inc.
161 Cheshire Lane, Suite 100
MINNEAPOLIS MN 55441

Re: K081379
Trade/Device Name: inReach System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 15, 2008
Received: May 16, 2008

Dear Mr. Kovach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081379

Device Name: inReach System

Indications for Use:

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Not for pediatric use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081379